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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,573	01/02/2002	Karen Anne Kelso	8830-14	9226

23973 7590 09/01/2004

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,573

Applicant(s)

KELSO, KAREN ANNE

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, has been withdrawn based on Applicant's amendment.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Malhotra et al. (5,212,008) in view of Bustard et al. (4,230,597) has been withdrawn based on Applicant's amendments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 11-14 under 35 U.S.C. 103(a) as being unpatentable over Malhotra et al. in view of Bustard has been withdrawn in light of Applicant's amendments.
5. The rejection of claims 3-4 and 15 under 35 U.S.C. 103(a) as being unpatentable over Malhotra and Bustard, as discussed above, and further in view of Applicant's admitted state of the prior art has been withdrawn in light of Applicant's amendments.

As necessitated by Applicant's amendments, the following rejections have been amended or added to incorporate the newly-added limitations of the amended claims:

6. Claims 1-2, 5-9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bass et al. (5,292,362) in view of Lentz et al. (5,851,229) and Malhotra et al.

Regarding claims 5-9, Bass et al. teaches the use of a crosslinked saccharide, such as dextran (col. 5, lines 9-17 and 28), as a watertight sealant for prosthetic material (col. 4, lines 15-18; col. 7, line 45) to coat implantable devices to enhance their strength and resistance to fluids, to seal pores in the weave of the material, and reduce thrombogenicity (col. 8, lines 6-11).

What Bass fails to specifically teach is a method of coating such medical devices with dextran or a means to crosslink the dextran.

Lentz is cited to teach a method of coating flexible vascular grafts (col 1, lines 5-7) with crosslinked polysaccharide sealants useful in forming a resorbable, substantially blood-tight barrier on the graft (paragraph bridging columns 3 and 4; col. 4, line 62). Lentz coats such grafts by impregnating with the polysaccharide and subsequently cross-linking the polysaccharide and heat-drying at 60 °C (examples; abstract).

Since Bass teaches coating medical devices with a dextran polysaccharide to yield a water-tight seal and Lentz teaches a method of impregnating grafts with polysaccharide and then cross-linking to yield a water-tight seal, Lentz would have reasonably

suggested the use of his coating method in the method of Bass to provide a means to coat specific medical devices with sealants.

What Bass in view of Lentz specifically fail to teach is the crosslinker used to provide the cross-linked dextran of Bass.

Malhotra, as outlined in the previous office action, teaches that urea-formaldehyde is used to crosslink dextran by including the urea-formaldehyde in the coating mixture and then heating.

Since Bass and Lentz together teach crosslinking/heat-drying dextran after coating grafts with the dextran, and Malhotra teaches that crosslinking dextran can be accomplished by incorporating urea-formaldehyde into the dextran coating mixture, Malhotra would have reasonably suggested adding the crosslinker to the coating mixture of Bass in view of Lentz. It would have been obvious to one of ordinary skill in the art to use the teachings of Malhotra in the method of Bass and Lentz to provide Bass and Lentz with an effective way to obtain the crosslinked dextran coating desired by Bass and Lentz to provide water-tight seals to implantable medical device grafts.

Regarding the added limitation that the crosslinked dextran formed has bonds "sufficiently labile to permit resorption at an appropriate rate for tissue ingrowth upon implantation...", Examiner notes that the crosslinked dextran of Bass would inherently have such sufficient bonds as the product and methods are the same as Applicant's. Examiner further notes that "sufficiently" and "appropriate" are relative terms.

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Lentz teaches that the graft material may be e PTFE (col. 4, line 13).

Lentz teaches that the crosslinked polysaccharide may be plasticized with glycerol (P bridging columns 7 and 8).

Lentz inherently teaches the grafts of claim 1 coated by the above method.

Regarding claim 2, the carboxymethyl dextran, amino dextran, and diethyl aminoethyl dextran taught by Malhotra are either naturally occurring or modified to contain reactive groups.

Regarding claims 11-14, Malhotra further teaches that the polymeric dextran is crosslinked by exposure to the crosslinking agent, i.e., the urea-formaldehyde, in water (col. 5, lines 21-25; col. 6, lines 25-30 and 38). Malhotra teaches use of the crosslinking agent at 0.1-10 percent by weight, the urea portion thereof expected to lie within the range of 2-25% claimed by Applicant. As show in Malhotra's examples, the coating mixture is then heated at 100 °C, lying within the range claimed by Applicant. What Malhotra fails to teach is the separate addition of urea, then formaldehyde to the dextran solution. However, Examiner notes that in general, the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat App. 1959). Therefore it would have been obvious to

one of ordinary skill in the art to split the step of exposing the dextran to urea-formaldehyde into two steps with the expectation of successful results.

Regarding the weight percentages of formaldehyde to urea, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to optimize the varying amounts of the constituents of the crosslinking agent.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

7. Claims 3-4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bass in view of Lentz and Malhotra, as discussed above, and further in view of Applicant's admitted state of the prior art.

Malhotra teaches a crosslinked dextran product, but fails to teach how dextran is originally made or its molecular weight.

Applicant disclosed on page 3 of the instant specification, that dextran is made by fermentation with the bacteria required by claim 3 to create a useful product with a molecular weight of 40,000.

Because Bass in view of Malhotra and Lentz teaches the use of dextran for treatment with a crosslinking agent and Applicant discloses that it is known that dextran is first produced by fermentation as discussed above, Applicant's admitted state of the prior art would have reasonably suggested that the dextran of Bass, Malhotra, Lentz was made by such a fermentation process. It would have been obvious to one of ordinary skill in

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the art to use the teachings of Applicant's admitted state of the prior art as a teaching of the source of Bass, Lentz, and Malhotra's dextran.

Response to Arguments

8. Applicant's arguments with respect to the withdrawn rejections have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 6/4/2004 regarding the Bass in view of Lentz and Malhotra rejection have been fully considered but they are not persuasive.

Applicant argues that Bass does not teach that the second component may be crosslinked dextran and that the only mention of dextran is as a viscosity modifier. Examiner disagrees.

Bass cites dextran as one of the cross-linked saccharides in col. 5, line 27.

Applicant argues that Bass and Lentz do not teach that the crosslinked saccharide may be crosslinked by urea condensation and that Lentz does not teach the use of dextran. Examiner agrees.

Examiner notes that Bass teaches coating prosthetics with cross-linked dextran, but does not provide the mechanism for cross-linking dextran or the particular coating method for coating prosthetics. Therefore, Examiner has cited Malhotra to teach a

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mechanism for cross-linking dextran, as outlined above, and Lentz to teach a suitable coating method for coating prosthetics with crosslinked saccharides, as outlined above. Each references used in combination is not required to teach all elements of the claims. The test of obviousness is not express suggestion of the claimed invention in any or all references but rather the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them. *In re Rosselet*, 347 F.2d 847, 146 USPQ 183 (CCPA 1965); *In re Hedges*, 783 F.2d 1038.

Applicant argues that one of ordinary skill in the art would not use Lentz's porous coating method for making the substantially non-porous coating of Bass or non-porous coating required by Applicant.

Examiner disagrees with this analysis.

Like Bass and like Applicant, Lentz teaches coating prosthetics to form a water-tight seal. The citation provided by Applicant (Lentz, col. 1, line 5-13) states that Lentz' method is used to coat porous grafts with the sealants of his invention to render them blood-tight, i.e., non-porous.

Applicant argues that Malhotra does not solve the deficiencies of Bass and Lentz because neither Bass nor Lentz suggests cross-linking dextran and because Malhotra is a document relating to ink jet technology.

Examiner disagrees.

Bass teaches cross-linked dextran, as cited above.

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Regarding Malhotra being directed to unrelated technology, Examiner argues that Malhotra was cited merely to provide a means to cross-link the dextran of Bass. The urea-formaldehyde condensation cross-linking agent, used by Malhotra to cross-link dextran, would inherently cross-link dextran in other technologies. One of ordinary skill in the art looking to find a crosslinker for providing cross-linked dextran, as required by Bass, would have looked to various technologies for such an agent. The field of endeavor for searching for a suitable dextran cross-linker is broader than only that which is encompassed by coated medical grafts.

Conclusion

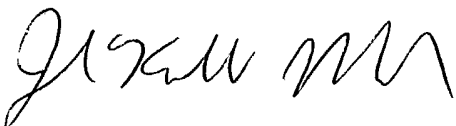
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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August 27, 2004